

THE PUBLIC SECTOR'S ROLE IN BIOTECHNOLOGY RESEARCH

The concept that the public sector has a major role to play in research — and particularly in agricultural research — is an historic one. It was part of the original mandate for the Department of Agriculture (USDA) in 1862, but perhaps its strongest expression came in 1887 with the passage of

the Hatch Act to establish the land-grant system of universities. Recognizing that it is in the public interest to supply funds to finance research, the land-grant philosophy of research, education, and public service has been the foundation of America's agricultural productivity for nearly 125 years.

Thus the acknowledgment by government — and the public — that agricultural research is a valuable use of tax dollars has an historic basis — and a foundation that has continued to be solid over the years as the investment is paid back many times in vital contributions to agriculture, to the consumer, and to the national economy.

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Overall, in the United States, the government has tended to take on the role of funding more fundamental research. Thus, not every project will have a clear end product, but maybe geared toward increasing our knowledge about the functioning of organisms at the cellular and molecular level. As a result, the public sector has played, and will continue to play, a major role in doing fundamental research which contributes to the foundation of the biotechnology industry.

High-risk research is also an area which is ripe for public funding. As part of their development, biotechnology firms are going through an evolution. Following an initial large investment of venture capital, there were hopes for the quick generation of substantial returns. But as the first flush of excitement and expectation has died down, reality has set in in terms of the time needed to get products out into the marketplace.

As companies become more market-oriented, universities and government are playing an increasingly central role in doing high-risk work. For example, not too many biotechnology firms are doing salt tolerance or drought tolerance research because there are uncertainties about whether it will work. Therefore, research on this important trait has fallen to the public sector.

In addition, I do not want to overlook the equally significant responsibility of the universities in training the young men and women who will become employees in the biotechnology industry and faculty in the universities. To meet the growing demand for qualified people to guide future technologies, we must attract top-notch young men and women to science and agriculture, train them well, and endeavor to increase the racial, cultural, and gender diversity of that brain pool. Young people are the lifeblood of any long-term research endeavor.

TECHNOLOGY TRANSFER

There is growing concern that although the U.S. is preeminent in basic research we fall behind other countries in turning that knowledge into products. While the movement of graduate and postdoctoral students from the university to industry has always been one way in which technology transfer is accomplished, the passage of the Federal Technology Transfer Act in 1986 was a major advance. It clearly established the appropriateness of government scientists working closely with industry to facilitate application of their research results.

Not only is the Agricultural Research Service (ARS) aggressively implementing the Act's provisions, but USDA has been directed by Congress to increase developmental research within ARS. In addition, I chair a task force which is developing specific mechanisms for promoting closer cooperative interaction among federal, state, university, and industrial scientists. Our goal is to facilitate the utilization of discoveries and inventions originating in USDA and State Agricultural Experiment Station Laboratories for the benefit of society.

REGULATORY UNCERTAINTY

The public sector has a role in two major issues that will determine the future of biotechnology: 1) regulatory uncertainty and 2) public perception.

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In terms of the public perception, it is part of our role as scientists and end users of technology to get across to the public the facts it needs to make informed decisions — to help people look at the big picture and weigh the long-term benefits and costs.

We have been working for the past year on developing a definition of the scope of organisms which should receive regulatory oversight. The publication of guidelines for field testing of “organisms with deliberately modified hereditary traits” — genetically modified organisms — was an example of how this definition could be used.

The regulatory framework for biotechnology should be based on sound scientific principles, in which oversight is commensurate with the level of risk. We have three major goals: 1) to avoid singling out recombinant-DNA technology as being any more risky than other procedures used to modify an organism; 2) to refrain from unduly hindering research with burdensome and unnecessary overregulation; and 3) to provide assurance to the public that there is adequate review prior to the release of modified organisms if we are unfamiliar with how they will affect the environment or health.

PUBLIC PERCEPTION

Some people feel that we should not use the term “genetically modified organisms” because it indicates there is risk. The issue is that there is already a public perception of risk — and to much of the public, perception is reality. This issue must be resolved or else the great potential of biotechnology will not be realized.

In terms of the public perception, it is part of our role as scientists and end users of technology to get across to the public the facts it needs to make informed decisions — to help people look at the big picture and weigh the long-term benefits and costs. I take exception to those who would paint biotechnology as competing with sustainable agriculture for funding. Sustainable agriculture is a systems approach to producing food and fiber efficiently, economically, and in harmony with the environment. As a systems approach, it needs input from ecologists, soil scientists, computer scientists, systems engineers, and economists.

It also needs molecular biologists and biotechnologists who now have the tools to ask questions about the molecular and biochemical basis of desirable traits such as disease and insect resistance and photosynthetic efficiency (we currently use less than one percent of the sun’s radiation). In addition, we can delete components in food that are detrimental to health and add others that are beneficial. Thus, biotechnology can help agriculture be sustainable, productive and nutritious.

Another mechanism for addressing public concerns is risk assessment research. For the first time, the Farm Bill explicitly directs USDA to support biotechnology risk assessment research. The bill directs the Secretary of Agriculture to establish a grant program to fund research on methods to confine introduced organisms, monitor their dispersal, study potential gene transfer, and investigate other areas in which biosafety information may be incomplete.

To support this research, USDA will designate one percent of its biotechnology research funding exclusively for risk assessment work. Although the Department is still looking at budget data and discussing the details of implementing this legislation, it is likely that the funding level for risk assessment research will be about \$1 million a year.

FUNDING

In closing, I would like to address the issue of funding for biotechnology research. In 1987, the National Research Council (NRC) published a report on *Agricultural Biotechnology — Strategies for National Competitiveness* which recommended that in order for agricultural biotechnology to reach its full potential, a \$500 million investment should be made in fundamental research in the agricultural biological sciences.

Congressman George Brown picked up on this recommendation and suggested a national institute of agriculture funded at the \$500 million level. Then, in 1989, the Board on Agriculture of the National Research Council published a report entitled *Investing in Research — A Proposal to Strengthen the Agricultural Food and Environmental System*.

These two NRC reports formed the basis for the National Research Initiative on Agriculture, Food, and the Environment. This initiative was launched in the President's FY1991 budget with a recommendation for funding in its first year at \$100 million and a commitment to add \$50 million in each of the outyears — provided that funds were appropriated on a non-earmarked basis. In the same year, Congress authorized funding of the initiative at the recommended level of \$500 million per year, reaching that amount of funding by 1995.

As you know, the authorization and appropriations process are two distinct activities. In FY 1991, Congress appropriated \$73 million, and in the

FY1992 budget currently being considered by the appropriations committees, the President has recommended funding at \$125 million. In addition, there is a \$25 million competitive facilities program which is an attempt to address the earmarking problem.

Although not all of these funds are dedicated to biotechnology, a considerable amount in the plant and animal systems areas will support basic work needed to effectively use the tools of biotechnology. In the \$35 million for plant systems, \$11 million is dedicated to map genes that regulate agriculturally important traits such as insect and disease resistance and drought tolerance. In the \$53 million recommended in FY 1992, \$18 million is recommended for genetic mapping.

FCCSET

There is also a new federal approach to research funding through the Office of Science and Technology Policy (OSTP) which operates the Federal Coordinating Committee of Science and Engineering Technology (FCCSET). The purpose of FCCSET is to bring together agencies across the government which have interest and expertise in a particular priority area — for example, global climate change. By “comparing notes,” so to speak, we establish a baseline picture of what is going on. We can see the overlaps — and the gaps.

Just as a doctor would use an X-ray to guide her in choosing a treatment, the baseline picture helps us develop a research plan. Each agency then develops that part of the plan in which it can make the best contribution. Furthermore, by bringing the Office of Management and Budget (OMB) into the planning stage, we can assure that each group’s part of the overall plan does become part of that agency’s budget. FCCSET is a successful strategy to coordinate research planning and budgeting and to establish national research priorities.

Last year, in addition to global climate change, FCCSET added two more areas to the planning process: high-performance computing, and science and mathematics education. While across government there is an overall attempt to keep the budget less than inflation, all three initiatives received increased funding in the President’s FY 1992 budget. When FCCSET met a few weeks ago, two other candidates were proposed for the planning process: advanced materials and processes, and biotechnology.

We will start out doing a “crosscut” to determine the current level of funding and then plan for the outyears of 1993 to 1995. It is too early to know whether this exercise will turn into an initiative as did global climate change, high-performance computing, and science and mathematics education, but this is the first step — which may then lead to a component in the President’s 1993 budget.

CONCLUSION

From ancient civilizations to our current technologically advanced society, national leaders have understood that new scientific knowledge can be a tremendous instrument of national strength and public good.

A strong national commitment to public funding of agricultural research, technology, and education is essential to the short- and long-term interests of both the U.S. and the world. Secretary of Agriculture Ed Madigan has stated (House testimony 4/17/91) that “like other sectors of the economy, agriculture is increasingly dependent upon technological advances to ... meet immediate and long-term challenges....”

The role of the public sector in helping agricultural research meet those challenges has historically been a central one — and it will surely remain so. I foresee the strong continuation of investment in publicly-funded agricultural biotechnology research in the United States, which I feel is essential to achieve the goals of an economically and environmentally sustainable agriculture.

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